

comparability review or a validation review inspection is not acceptable, as described under § 493.573 and § 493.575, or if the State of Washington fails to pay the required fee every 2 years as required under § 493.646.

Laboratory Data

In accordance with our regulations at § 493.557(b)(8), the approval of this exemption for laboratories located in and licensed by the State of Washington is conditioned on the State of Washington's continued compliance with the assertions made in its application, especially the provision of information to us about changes to a laboratory's specialties or subspecialties based on the state's survey, and changes to a laboratory's certification status, such as a change from a CLIA certificate of compliance to a CLIA certificate of waiver.

Required Administrative Actions

CLIA is a user-fee funded program. The registration fee paid by laboratories is intended to cover the cost of the development and administration of the program. However, when a state's application for exemption is approved, we do not charge a fee to laboratories in the state. The state's share of the costs associated with CLIA must be collected from the state, as specified in § 493.645.

The State of Washington must pay for the following:

- Costs of federal inspections of laboratories in the state to verify that Washington State's laboratory licensure program requirements are equivalent to or more stringent than those in the CLIA program, and that they are enforced in an appropriate manner. The average federal hourly rate is multiplied by the total hours required to perform federal validation surveys within the state.
- Costs incurred for federal surveys, including investigations of complaints that are substantiated. We will bill the State of Washington on a semiannual basis.
- The State of Washington's proportionate share of the costs associated with establishing, maintaining, and improving the CLIA computer system, based on the portion of those services from which the State of Washington received direct benefit or which contributed to the CLIA program in the state. Thus, the State of Washington is being charged for a portion of our direct and indirect costs of administering the CLIA program. Such costs will be incurred by CMS, the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) and contractors

working on behalf of these respective agencies.

To estimate the State of Washington's proportionate share of the general overhead costs to develop and implement CLIA, we determined the ratio of laboratories in the state to the total number of laboratories nationally. Approximately 1.5 percent of the registered laboratories are in the State of Washington. We determined that a corresponding percentage of the applicable CMS, CDC, FDA, and their respective contractor costs should be borne by the State of Washington.

The State of Washington has agreed to pay the state's pro rata share of the anticipated overhead costs and costs of actual validation (including complaint investigation surveys). A final reconciliation for all laboratories and all expenses will be made. We will reimburse the state for any overpayment or bill it for any balance.

II. Approval

In light of the foregoing, we grant approval of the State of Washington's laboratory licensure program under subpart E. All laboratories located in and licensed by the State of Washington under the Medical Test Site law, Chapter 70.42 of the Revised Code of Washington, are CLIA-exempt for all specialties and subspecialties until September 27, 2019.

Authority: Section 353(p) of the Public Health Service Act (42 U.S.C. 263a).

Dated: August 8, 2013.

Marilyn Tavenner,
Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2013-23659 Filed 9-26-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0656]

Secure Supply Chain Pilot Program; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the **Federal Register** of August 20, 2013 (78 FR 51192). The document announced the start of the Secure Supply Chain Pilot Program (SSCPP). The document was published with an incorrect email address for the SSCPP mailbox. This document corrects that error.

FOR FURTHER INFORMATION CONTACT:

Katharine Neckers, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Building 51, Rm. 4259, 301-796-3339, email: Katharine.Neckers@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In FR Doc. 2013-20215, appearing on page 51192 in the **Federal Register** of August 20, 2013, the following correction is made:

On page 51194, in the second column, under "IV. Process for Applying to Participate in the Pilot," in the third full paragraph, the sentence that reads "For communications other than the submission of the SSCPP application (Form FDA 3676), please contact the CDER SSCPP mailbox at SSCPPMailbox@fda.hhs.gov" is corrected to read "For communications other than the submission of the SSCPP application (Form FDA 3676), please contact the CDER SSCPP mailbox at CDERSSCPP@fda.hhs.gov."

Dated: September 24, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-23563 Filed 9-26-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 30-Day Comment Request; Evaluation of a Kidney Disease Education and Awareness Program in the Hispanic Community

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on July 19, 2013, Volume 78, pages 43214-43215, and allowed 60-days for public comment. One public comment was received. The purpose of this notice is to allow an additional 30 days for public comment. The National Kidney Disease Education Program, the National Institute of Diabetes and Digestive and Kidney Diseases, the National Institutes of Health (NIH), may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, *OIRA submission @ omb.eop.gov* or by fax to 202-395-6974, Attention: NIH Desk Officer. To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Eileen Newman, Associate Director, National Kidney Disease Education Program, OCPL, NIDDK, NIH, Building 31, Room 9A06, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number (301) 435-8116 or Email your request, including your address to: *Eileen.newman@nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are

best assured of having their full effect if received within 30 days of the date of this publication.

Proposed Collection: Evaluation of a Kidney Disease Education Program with Promotores in the Hispanic Community, 0925—NEW, National Kidney Disease Education Program, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH).

Need and Use of Information Collection: NKDEP is developing a kidney disease education program to raise awareness among the Hispanic community at risk for kidney disease. Since diabetes is the most common cause of kidney disease, the program is being developed for inclusion in existing diabetes programs being conducted by “promotores de salud” (Spanish/English-speaking community health workers). A pilot evaluation will assess: (a) Overall quality of the program from the client and promotor/a perspective, including strengths and weaknesses of the program and the

training, and areas for program improvement; (b) effectiveness of the program on the clients (the community members being educated); and (c) effectiveness of materials and training, including promotores’ ability to deliver education to the client and administer the client pre-test/post-test surveys. The pilot study will deliver strategic and actionable guidance for refining the educational and training materials for national dissemination. Based on outcomes from the pilot study, a national evaluation is planned that will use the client pre-test/post-test surveys to assess: (a) Knowledge gains about kidney disease, (b) awareness of NKDEP resources and importance of kidney health, (c) reported behavior change outcomes and (d) reported health status.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 101 (see table below).

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondent | Form name | Number of respondents | No. of responses per respondent | Response burden (hours) | Total burden hours |
|---|---|-----------------------|---------------------------------|-------------------------|--------------------|
| Pilot study collection: Promotores | Promotores training pre-test, post-test, and qualitative in-depth interview post client session (Attachment 1 and 2). | 12 | 1 | 5/60 | 1 |
| Promotores | Administer client pre-test, post-test, and second post-tests for experimental and control groups (Attachment 3). | 20 | 17 | 15/60 | 85 |
| Client Group | Client pre-test, post-test, second post-test for experimental and control groups (Attachment 3). | 85 | 1 | 10/60 | 14 |
| Client Group (partial) | Client qualitative in-depth interview post-client session (Attachment 4). | 4 | 1 | 10/60 | 1 |
| Total | | 121 | | | 101 |

Dated: September 23, 2013.

Camille M. Hoover,

Executive Officer, NIDDK, NIH.

[FR Doc. 2013-23673 Filed 9-26-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; HIV Vaccine Research and Design.

Date: October 21–22, 2013.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, Regency Ballroom, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Kelly Y. Poe, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 6700-B Rockledge Drive, MDS-7616, Bethesda, MD 20892, 301-451-2639, *poeky@niaid.nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Peer Review Meeting.

Date: October 21–23, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: Residence Inn Bethesda, Montgomery I & II, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Maja Maric, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, DHHS/NIH/NIAID, 6700B Rockledge Drive,